

Food and Drug Administration, HHS

§ 868.5870

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5790 Tracheal tube stylet.

(a) *Identification*. A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5795 Tracheal tube cleaning brush.

(a) *Identification*. A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[51 FR 40388, Nov. 6, 1986]

§ 868.5800 Tracheostomy tube and tube cuff.

(a) *Identification*. A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) *Classification*. Class II.

[51 FR 40389, Nov. 6, 1986]

§ 868.5810 Airway connector.

(a) *Identification*. An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5820 Dental protector.

(a) *Identification*. A dental protector is a device intended to protect a patient's teeth during manipulative procedures within a patient's oral cavity.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5830 Autotransfusion apparatus.

(a) *Identification*. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

(b) *Classification*. Class II (performance standards).

§ 868.5860 Pressure tubing and accessories.

(a) *Identification*. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5870 Nonbreathing valve.

(a) *Identification*. A nonbreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

(b) *Classification*. Class II (performance standards).